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Re-evaluation Note REV2013-17

Re-evaluation Project Plan for Clodinafop Propargyl

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In Canada, clodinafop propargyl is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrants of clodinafop propargyl were notified of the initiation of the re-evaluation of clodinafop propargyl. Following this, the registrants of clodinafop propargyl technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial class products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated areas of focus related to the re-evaluation of clodinafop propargyl.

Clodinafop propargyl is an herbicide that has been registered in Canada since 1995. It is currently registered for use in spring and durum wheat to control certain grass weeds (Use-Site Categories 13 and 14). Registered clodinafop propargyl end-use products are formulated as emulsifiable concentrates, to be applied by ground or aerial equipment.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of clodinafop propargyl, as well as additional data required. Should additional information become available during the re-evaluation period that affects the regulatory status of clodinafop propargyl, the PMRA will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for clodinafop propargyl is anticipated to be published in 2016.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for clodinafop propargyl was considered complete at the time of initial registration. Data generated since the time of the original submission (for example, a developmental neurotoxicity study) and data previously unavailable, but that may impact the hazard assessment, will be evaluated. Verification of the points of departure used for occupational and dietary risk assessment will be undertaken. Areas not addressed in the original evaluation (for example, consideration of an acute reference dose, application of the *Pest Control Products Act* factor) will be reviewed. Recent scientific literature and incident reports will also be incorporated into the re-evaluation.

The dietary exposure and risk assessments previously conducted to support the registered uses of clodinafop propargyl will be re-evaluated to ensure they meet current science standards and policies. In particular, the dietary exposure assessment will be updated to reflect current data including available residue data from surveillance programs, drinking water estimated environmental concentrations, new food consumption data, and the incorporation of revised toxicological reference doses, if applicable.

Since there are no registered residential uses for clodinafop propargyl, a residential risk assessment is not required.

The occupational exposure and risk assessments of clodinafop propargyl will be revised to reflect the currently available scientific data and approaches, as well as revised toxicological endpoints and margins of exposure, if applicable. In the absence of chemical-specific data, standard defaults will be used in the occupational exposure and risk assessments. In addition, a review of any available incident reports will be completed.

Environmental Risk Assessment

Environmental risk assessments will be updated, where appropriate, using current methodologies, available scientific data and relevant literature.

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements.

Buffer zones for the protection of sensitive terrestrial and aquatic habitats will be calculated based on current practices and taking into consideration currently registered uses.

The Toxic Substances Management Policy will be taken into consideration.

Environmental fate will be reviewed to determine drinking water and expected environmental concentrations for risk assessment purposes

Value

The value of clodinafop propargyl will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology and the environment have been identified for clodinafop propargyl and were requested from the technical registrants (Appendix I).

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for clodinafop propargyl is anticipated to be published for consultation in 2016.

Additional Information

PMRA documents can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca

Appendix I Data Requirements for the Re-evaluation of Clodinafop Propargyl

DACO 4.2.9 Other Acute Studies (subacute oral)
DACO 4.3.5 Short-term Dermal (21/28-day)
DACO 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay
DACO 4.5.7 Genotoxicity: In vivo Cytogenetics
DACO 4.5.8 Other Genotoxicity Studies (dominant lethal test)
DACO 9.2.7 Other terrestrial invertebrates (beneficial insects)
DACO 9.3.4 Laboratory Studies with Other Species (Sediment dwelling species - due to potential benthic risk)